

REMARKS

Claims 14-80 are pending. The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. The limitation of claim 15 is incorporated in claim 14. New claim 36 is based on claim 14 as amended and claim 19. New claim 56 is based on claim 14 as amended with the further limitation that the oil is extracted using a solvent; support for such use may be found, inter alia, at page 11, lines 14-15, of the specification. Similarly, support for claims 67-70 may be found, inter alia, at page 11, lines 15-17, of the specification. The limitation added to claim 29 (and the analogous claims 49 and 74) is based, inter alia, on page 11, lines 29-32, of the specification.

Claims 1-8 and 11-12 are canceled without prejudice or disclaimer to their prosecution in a divisional application. Their subject matter (i.e., a novel and nonobvious pasteurization process) was restricted by the Examiner in a prior Office Action.

35 U.S.C. 101 –Utility

Claims 14-34 were rejected under Section 101 as they are allegedly directed to non-statutory subject matter. Applicants traverse.

The oil is at least “isolated” or “extracted” to clarify that the claimed product is manufactured (i.e., made by the hand of man).

Withdrawal of the Section 101 rejection is requested because the pending claims are directed to statutory subject matter.

35 U.S.C. 112 – Definiteness

Claims 29-35 were rejected under Section 112, second paragraph, as they are allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants traverse.

Process steps are recited in claim 29. Support for the limitations may be found, inter alia, at page 11, lines 29-32, of the specification.

Applicants request withdrawal of the Section 112, second paragraph, rejection because the pending claims are clear and definite.

35 U.S.C. 102 – Novelty

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 14-35 were rejected under Section 102(b) as allegedly anticipated by Bijl et al. (WO 97/37032) in light of Beudeker et al. (WO 99/65327). Applicants traverse.

Applicants' claimed invention requires a microbial oil comprising at least 35% of arachidonic acid, which has an anisidine value (AnV) of less than 25. WO 97/37032 does not disclose a microbial oil satisfying the aforementioned limitations. Indeed, Bijl et al. mention an oil having an AnV < 5, but there is no teaching or suggestion of an oil comprising at least 35% of arachidonic acid and having an AnV of less than 25. In fact, Bijl et al. do not mention the arachidonic acid content of their oils at all, and there is no reason to believe that Bijl et al. obtained an oil using their disclosed process that would satisfy both of the aforementioned limitations.

Microbial oils having a high concentration of at least 35% arachidonic acid (ARA) are sensitive to oxidation due to the latter's high concentration and the number of unsaturated bonds present in ARA (i.e., four double bonds per molecule of ARA). Accordingly, an oil having at least 35% ARA (e.g., the claimed product) has a significantly higher sensitivity to oxidation than an oil having a lower concentration of ARA (e.g., oil disclosed in Bijl et al.). Applicants provide an oil having both high ARA content (i.e., at least 35% ARA) as well as high oxidative stability (as expressed by an anisidine value less than 25). The prior art neither teaches nor suggests such oil.

Since the disclosure of Bijl et al. is silent on the ARA content of their oil, the Examiner appears to be reading the ARA content into Bijl et al. using the disclosure of the Beudeker et al. document. One skilled in the art would find such combination of documents clearly improper. Beudeker et al. state, "[The] oil may have at least 10%, such as at least 20%, preferably at least 30%, advantageously at least 35% and optimally at

least 40% ARA” (page 4, lines 1-2). But nowhere in Beudeker et al. is there any reason for one skilled in the art to believe that this disclosure of possible ARA content describes the oil of Bijl et al. While an oil might (or might not) comprise ARA in any of the percentages disclosed by Beudeker et al., there is no reason provided by the cited documents or in the Office Action that the oil of Bijl et al. comprises at least 35% ARA.

In view of the above, it is submitted that although Beudeker et al. disclose oils containing 10% to 40% ARA, Bijl et al. do not disclose an oil comprising at least 35% ARA. The cited documents certainly do not teach or suggest an oil comprising at least 35% ARA and having an AnV of less than 25. Evidence is also lacking that the oils discussed in the two documents are the same or would have been expected to have equivalent properties. Note that inherency must be a necessary result, not merely a probability or possibility. See *Continental Can Co. v. Monsanto Co.*, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (“Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”) quoting *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981). Beudeker et al. and the discussion in the Office Action do not provide an reasoned basis for concluding that the missing disclosure of “at least 35% arachidonic acid” is necessarily present in Bijl et al. Here, since the process disclosed by Applicants in their application was not taught or suggested in the prior art, the different process disclosed by Bijl et al. would not obtain an oil combining the properties of “comprising at least 35% of arachidonic acid” and “having an anisidine value of less than 25” as claimed herein. In the absence of acceptable and adequate evidence (e.g., why would the skilled artisan have expected that the oil of Bijl et al. possessed the aforementioned combination of properties?), an anticipation rejection based on the doctrine of inherency cannot stand. *In re Robertson*, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999) quoting *Continental Can*, 20 USPQ2d at 1749.

The cited document WO 97/37032 does not anticipate the pending claims since it does not disclose all limitations of independent claims 14, 36 and 56. Moreover, claims depending from the independent claims are also not anticipated by Bijl et al. because

the limitations of the independent claims are incorporated in claims depending therefrom. See *In re McCarn*, 101 USPQ 411, 413 (C.C.P.A. 1954).

Withdrawal of the Section 102 rejection is requested because the cited document fails to disclose all limitations of the claimed invention.

Conclusion

Having fully responded to the Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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